# GOOD CARE POVIDONE IODINE - povidone-iodine swab Dalian Goodwood Medical Care Ltd.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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#### Povidone Iodine, USP Swabsticks

Active Ingredient

Povidone Iodine USP, 10% w/v

(equivalent to 1% titratable iodine)

Purpose

Antiseptic

Uses

- Health-care antiseptic for preparation of the skin prior to surgery
- First aid antiseptic to help prevent the risk of skin infection in minor cuts, scrapes and burns

#### Warnings

For external use only.

Do not use or apply in the eyes

- on individuals who are allergic or sensitive to iodine
- over large areas of the body
- as a first aid antiseptic longer than 1 week unless directed by a doctor

Discontinue use if irritation and redness develop.

Stop use and consult a doctor if the condition persists or gets worse.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

For preparation of the skin prior to surgery clean the affected area, remove swab by the stick, apply to the operative site prior to surgery.

For use as a first aid antiseptic clean the affected area, apply a small amount of this product on the area 1-3 times daily. May be covered with a sterile bandage. If bandaged, let dry first.

Other information

Store at room temperature: 15 degrees - 30 degrees C (59 degrees - 86 degrees F)

Inactive ingredients

citric acid, glycerin, nonoxynol-8, purified water, sodium hydroxide

Manufactured by DALIAN GOODWOOD MEDICAL CARE LTD.

3-91 Jiulicun Yongzheng Street Jinzhou District Dalian China 116100

Tel: +86-411-87857288

Made in China www.dl-goodwood.com

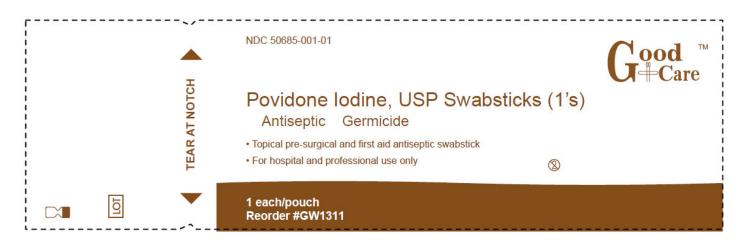
Good Care

#### Povidone Iodine, USP Swabsticks

#### Antiseptic Germicide

- Topical pre-surgical and first aid antiseptic swabstick
- For hospital and professional use only





#### GOOD CARE POVIDONE IODINE

povidone-iodine swab

| Product Information     |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:50685-001 |
| Route of Administration | TOPICAL        | DEA Schedule       |               |

| Active Ingredient/Active Moiety  |                          |                 |  |
|--|--------------------------|-----------------|--|
| Ingredient Name  | <b>Basis of Strength</b> | Strength        |  |
| PO VIDO NE-IO DINE (UNII: 85H0 HZU99 M) (PO VIDO NE-IO DINE - UNII:85H0 HZU99 M) | POVIDONE-IODINE          | 10 mL in 100 mL |  |

| Inactive Ingredients                           |          |
|--|----------|
| Ingredient Name                                | Strength |
| CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP) |          |

| GLYCERIN (UNII: PDC6A3C0OX)           |  |
|---------------------------------------|--|
| WATER (UNII: 059QF0KO0R)              |  |
| SO DIUM HYDRO XIDE (UNII: 55X04QC32I) |  |

| Packaging |                  |                     |                      |                    |
|-----------|------------------|---------------------|----------------------|--------------------|
| #         | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
| 1         | NDC:50685-001-01 | 2 mL in 1 POUCH     |                      |                    |
| 2         | NDC:50685-001-03 | 5.5 mL in 1 POUCH   |                      |                    |

| Marketing Information   |  |                      |                    |  |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |
| OTC monograph not final | part333A                                 | 10/01/2010           |                    |  |
|                         |  |                      |                    |  |

## Labeler - Dalian Goodwood Medical Care Ltd. (529575699)

### Registrant - Dalian Goodwood Medical Care Ltd. (529575699)

| Establishment                     |         |           |                            |  |
|-----------------------------------|---------|-----------|----------------------------|--|
| Name                              | Address | ID/FEI    | <b>Business Operations</b> |  |
| Dalian Goodwood Medical Care Ltd. |         | 529575699 | manufacture                |  |

Revised: 3/2011 Dalian Goodwood Medical Care Ltd.